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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,090	11/15/2001	Gordhanbhai Patel	PATL3.0-010	6317
1815	7590	12/09/2003	EXAMINER	
SELITTO, BEHR & KIM 203 MAIN STREET METUCHEN, NJ 08840-2727			CROSS, LATOYA I	
			ART UNIT	PAPER NUMBER

1743

DATE MAILED: 12/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

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**Office Action Summary**

Application No.

10/009,090

Applicant(s)

PATEL

Examiner

LaToya I. Cross

Art Unit

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-- **Th MAILING DATE of this communication appears on th cover sheet with th correspond nc address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 November 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-25 and 27-41 is/are rejected.
- 7) ☐ Claim(s) 26 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                      | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                             | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3/26/02</u> | 6) <input type="checkbox"/> Other:  |

## DETAILED ACTION

### *Specification*

1. The disclosure is objected to because of the following informalities:

Several pages of the specification have been numbered incorrectly. Page 37 should be page 32. Page 38 should be page 36. Applicants should make these corrections so that the pages are numbered consecutively. Also, at page 20, line 16 'he' should be corrected to read "The". Headings 5, 8 and 9, found at pages 19-20, have no explanations under the headings. They should be deleted so as to not be confusing.

Appropriate correction is required.

### *Claim Observations*

Claim 10 mentions the term "styrene" twice.

Claim 21 mentions the term "acid" twice.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-21, 24, 27-41 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,287,518 to Ignacio et al.

Ignacio et al teach a composition and device for monitoring sterilization processes. The composition comprises a dye (indicator) and a halogen source (activator) within a binder resin (polymer), as recited in claim 1 (col. 3, lines 8-9). The dye is one that is susceptible to halogenation, as recited in claim 5. Phenol red, a pH indicator, is taught as an example, as recited in claims 3 and 4 (col. 3, lines 10-19). With respect to claim 6, Ignacio et al teach an example of a sterilization monitoring composition where phenol red is used as the indicator. After exposure to peracetic acid, the composition turned from red to yellow (col. 10, line 66 – col. 11, line 15). With respect to the binders recited in claims 7-14, Ignacio et al teach several polymers including celluloses (col. 40-53). With respect to the activator, Ignacio teaches halogen sources including as alkali metal halides such as potassium bromide, as recited in claims 16-19 (col. 3, lines 31-39). The reference also teaches using quaternary amines, such as tetra alkyl ammonium bromides, as recited in claims 20 and 21 (col. 6, lines 57-60). With respect to claim 24, Ignacio et al teach using a microporous bottom (40) which helps control the amount of vapor that contacts the indicator composition (col. 10, lines 18-19). With respect to claims 27 and 28, figure 1 of the reference shows a multi-layered device wherein the top layer (30) is made of polymeric material (col. 10, lines 4-6). With respect to claims 30-36, where Applicants claim the process of making the device, Ignacio teaches dissolving the components of the composition in an alcohol solvent and applying the composition to blotter paper (col. 4, lines 38-62). The composition may be in the form of ink and the substrate may be in the form of a strip or label (col. 3, line 64 – col. 4, line 19). With respect to claims 37-41, where Applicants claim the use of the device in monitoring sterilization processes, Ignacio et al teach that the device may be used to monitor peracetic acid or peroxide sterilization processes.

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***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 22, 23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ignacio et al in view of EP 0356116 to Suto.

The disclosure of Ignacio et al is described above. Ignacio et al differ from the instantly claimed invention in that there is no teaching of thiocyanates in the sterilization monitoring compositions. Ignacio et al also fail to teach the use of plasticizers in the composition.

Suto teaches compositions useful in monitoring sterilization processes. The reference teaches that thiocyanates, sodium thiocyanate in particular, aid in accelerating the reaction of the indicator to form an observable color change (page 3, lines 42-49). It would have been obvious to one of ordinary skill in the art to include sodium thiocyanate in the composition of Ignacio et al to activate the indicator and allow the color reaction to proceed faster and quickly alert the user as to the accuracy of the sterilization process.

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With respect to the use of plasticizers, Suto teaches that plasticizers are commonly added to ink compositions used in sterilization processes. It would have been obvious to one of ordinary skill in the art to add a plasticizer to the composition of Ignacio et al to modify the manner in which vapor contacts the indicator composition.

*Allowable Subject Matter*

7. Claim 26 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art of record fails to teach or suggest including zinc compounds or polyaziridine into sterilization compositions to aid in controlling the diffusion of vapor gases.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 703-305-7360. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 703-308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

LIC

November 27, 2003

  
Jill Warden  
Supervisory Patent Examiner  
Technology Center 1700